Standard Operating Procedure – Study Close and Lock SOP

This cover sheet controls the layout and components of the entire document.

Issued Date: October 30, 2006

Effective Date: December 11, 2006

Department Approval:

Peter Covitz

Chief Operating Officer, NCICB

QA Approval:

George Komatsoulis

Director of Quality Assurance

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	November 22, 2005	SOP WG Review	All pages	Document Creation
1.0	December 13, 2005	SOP WG Approval	All pages	Document Creation
1.0	January 10, 2006	BP SIG Approval	All pages	Document Creation
1.0	October 30, 2006	BP SIG/SOP WG	All pages	Initial release.

1. Purpose

This Study Close Standard Operation Procedure (SOP) describes the processes to close and or lock a clinical research trial. This SOP covers activities conducted by clinical data management prior to closing the clinical database temporarily to support interim analysis and DSMB requests, as well as the final lock for end of study reporting requirements and archival.

2. Scope

This SOP applies to all clinical research trials covered under the caBIG™ environment and sponsored by the National Cancer Institute (NCI).

3. Requirements

3.1 The study may be "closed" for analysis, where write access to the clinical research data is temporary restricted, to support analysis (interim) activities.

3.2 The study may be "locked" for final analysis and report, where write access to the clinical research data is permanently restricted. This allows for final analysis and report of clinical research data, prior to archiving.

3.3 All active clinical research subjects must complete their final visit and any follow-up visit activities prior to lock of the research study for final analysis and reporting.

3.4 All coding of clinical events must be complete prior to study lock.

3.5 Reconciliation of the Serious Adverse Event system or database must be complete prior to study lock.

3.6 All external data in support of the clinical research trial must be loaded into the clinical database and cleaned prior to study lock (i.e., laboratory data, other electronic data, when applicable).

3.7 All outstanding queries or questions to the investigator or site personnel must be resolved and the clinical database updated, according to conventions outlined in the Clinical Data Management Plan (if applicable) or in compliance with the protocol prior to study lock.

3.8 For study close, the coding of events, reconciliation of the serious adverse event database, loading of external data, cleaning of data, and entering patient data to support an interim analysis, will be determined by the clinical study team and/or other appropriate regulatory authorities, based on their procedures to support an 'interim analysis' population of study patients.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	CR-002	SOP for Conduct of a Clinical Research Study
4.3	CR-006	SOP for Coding of Clinical Research Data
4.4	CR-007	SOP for Reconciliation of SAEs
4.5	CR-013	SOP for Statistical Analysis Plan
4.6	CR-012	SOP for Study Reports ISS/ISE Format under the caBIG™ Program
4.7	CR-011	SOP for Breaking the Statistical Blind

5. Roles & Responsibilities

Role	Responsibility
Study Coordinator	• Ensure that all required actions are performed prior to database close, for temporary restriction of access to the clinical trial data, or final lock of clinical trial research data. • Collect, manage, and retain clinical trial research documentation in support of the clinical research trial.
Study Statistician	• Log and track all analysis related documentation and activities that occur after the clinical database is closed or locked and data are exported or extracted from the clinical trials database for analysis and reporting.
Clinical Data Manager	• Review all data for completeness according to the Clinical Data Management Plan (if applicable) or in accordance with the Protocol.
Programmer	• Close or lock clinical trial research study upon the request by the Study Coordinator. • Create data exports or extracts to support analytical and reporting by the Statistician. • Fully test all analytical programs created to support analysis and reporting requirements. • Manage all programs for analysis as planned.
Local QA	• Perform audit of the clinical trial research data. • Work with clinical data management, Study Coordinator, and/or Statistician to resolve any outstanding data issues prior to close or lock of the clinical research study.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all clinical data management system adopters that plan, design, and conduct clinical research trials. The attachments can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

TITLE	DESCRIPTION
1) Procedure Description for Study Close	This document provides instructions for close of a clinical research study. It provides step-by-step guidance to ensure that all studies are closed and re-opened, if required, in a consistent and controlled manner.
2) Procedure Description for Study Lock	This document provides instructions for the locking of a clinical research study. It provides step-by-step guidance to ensure that all studies are locked and archived in a consistent and controlled manner.
3) Study Lock Checklist	This document is an easy to follow checklist of the activities which must be completed prior to locking a clinical research database.
4) Process Flow for Study Close	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Study Close.
5) Process Flow for Study Lock	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Study Lock.